JACC Vol. 23, No. 2
February 1994:330–5

Coronary Perforation After Excimer Laser Coronary Angioplasty: The Excimer Laser Coronary Angioplasty Registry Experience

DAVID R. HOLMES, JR., MD, FACC, GUY S. REEDER, MD, FACC,
ZIYAD M. B. GHAZZAL, MD, FACC* JOHN F. BRESNAHAN, MD, FACC,
SPENCER B. KING III, MD, FACC,* MARTIN B. LEON, MD, FACC,† FRANK LITVACK, MD, FACC‡
Rochester, Minnesota; Atlanta, Georgia; Washington, D.C.; and Los Angeles, California

Objectives. **This study assessed the frequency of perforation with excimer coronary angioplasty.**

Background. **Coronary artery perforation after conventional percutaneous transluminal coronary angioplasty is extremely rare. Because laser coronary angioplasty involves actual tissue ablation, it has an increased potential for perforation.**

Methods. **All patients in the Excimer Laser Coronary Angioplasty Registry were included in this prospective study. Those who had a perforation related to the procedure were compared with those who did not have this complication.**

Results. **Of 2,759 consecutive patients in the Excimer Laser Coronary Angioplasty Registry, 36 (1.3%) had perforation. In these patients, the left anterior descending coronary artery was the most frequently treated vessel (53%). There were no differences in fiber sizes between patients with and those without perforation. Among the patients with perforation, 36.1% required coronary artery bypass surgery, 16.7% experienced an infarction and 5.6% had a fatal outcome. Among the patients without perforation, the rates were 3.1%, 3.8% and 0.6%, respectively. However, 41.7% of the patients with documented coronary artery perforation did not need coronary artery bypass surgery or experience myocardial infarction or death. No angiographic characteristics distinguished lesions with from those without perforation. The frequency of coronary artery perforation declined over time with increasing operator experience, from 1.6% in the first 1,888 patients to only 0.4% in the last 1,000 patients ($p = 0.002$).**

Conclusions. **With increasing operator experience, the rate of perforation with excimer laser coronary angioplasty has decreased. When perforation occurs, subsequent event rates increase.**

(J Am Coll Cardiol 1994;23:330–5)

The mechanism of percutaneous transluminal coronary angioplasty involves mechanical barotrauma, with vessel stretch and resultant plaque and intimal or medial fissures or cracks. Arterial perforation as a result of this mechanical stretch injury, although reported anecdotally, is extremely rare (1–8). New interventional technologies are now being widely used for the treatment of coronary artery disease. The mechanism of action of these new devices is different. For example, laser angioplasty involves actual tissue ablation and the production of acoustic shock waves (9,10). It thus has the potential for arterial wall perforation (10,11). Information is still limited on the incidence of perforation, the factors associated with it and the outcome of the procedure (12–14). The purpose of this Excimer Laser Coronary Angioplasty Registry report is to assess coronary artery perforation occurring with this procedure.

Methods

Laser system. The laser system is a 308-nm xenon chloride pulsed excimer laser that is magnetically switched with a pulse duration ≥200 ns (Advanced Interventional Systems) (13,15,16). This system operates on a single 220-V line, with a laser output ≥200 mJ/pulse at up to 20 to 30 Hz using catheter distal tip energy levels of 35 to 60 mJ/mm^2. During this Registry experience, three over-the-wire multifiber catheters were used with diameters of 1.3 mm (4F), 1.6 mm (4.7F) and 2.0 mm (6F).

Study patients. Beginning in 1988, excimer laser coronary angioplasty was tested for the treatment of coronary artery disease at participating centers (Appendix) after approval by the institutional review boards. Informed consent was obtained from each patient. Criteria for patient selection included symptomatic or documented ischemia in the setting of coronary artery stenoses that could be accessed by the guide wire and laser catheter.

All patients at each center who underwent laser treatment were included in this study. For each patient, clinical and anatomic data and details and outcome of the procedure

From the Division of Cardiovascular Diseases and Internal Medicine, Mayo Clinic and Mayo Foundation, Rochester, Minnesota; *Division of Cardiology, Emory University Hospital, Atlanta, Georgia; †Washington Hospital Center, Washington, D.C.; and ‡Cedars-Sinai Medical Center, Los Angeles, California. Drs. Ghazzal and King have a royalty arrangement with Advanced Interventional Systems, Inc., Irvine, California involving a catheter not used in this study. Dr. Litvack has a financial interest in the same company.

Manuscript received February 16, 1993; revised manuscript received September 21, 1993, accepted September 22, 1993.

Address for correspondence: Dr. David R. Holmes, Jr., Mayo Clinic, 200 First Street SW, Rochester, Minnesota 55905.

0735-1097/94/$7.00

were prospectively collected in the central Excimer Laser Coronary Angioplasty Registry.

This study identified patients who had a perforation related to the procedure. The outcome of these patients was compared with that of patients who underwent laser angioplasty but did not have this complication. After a perforation was identified, subsequent management decisions were at the discretion of the responsible cardiologist and were not dictated by any common protocol.

Procedure. Standard percutaneous techniques were used. Selection of catheter size was at the discretion of each operator but depended on the size of the target lesion and vessel. General recommendations included use of a 1.3-mm catheter in a vessel of ≥1.8-mm diameter, a 1.6-mm catheter in a vessel of ≥2.3-mm diameter and a 2.0-mm catheter in a vessel of ≥3.0-mm diameter. After the stenosis or occlusion was crossed, the catheter was advanced immediately proximal to the lesion, and lasing was initiated. During lasing, the catheter was advanced at approximately 1 mm/s. After the initial lasing, operators could stop if the result was satisfactory, sequentially increase the catheter size or switch to conventional angioplasty.

Periprocedural medications included heparin (10,000 to 15,000 U), aspirin (usually given before and continued after the procedure), nitrates (both sublingual and parenteral during the procedure) and calcium channel antagonists.

Throughout the course of this Registry experience, there were periodic investigator meetings to discuss patient selection and complications. The limited number of perforations were discussed often and in some detail. On the basis of observations made by the investigators from their own practice experiences—and theoretic concerns about lasing normal arterial wall—bifurcation lesions, severely eccentric lesions and severely angulated lesions were thought to be at risk, as were chronic total occlusions, in which there was concern that the guide wire might be intramural rather than intraluminal. Investigator concerns and discussion of individual anecdotal cases led operators to become more cautious in approaching these subsets of lesions. In addition, the importance of not lasing when the catheter could not be advanced was recognized.

Angiographic assessment. Orthogonal views of the coronary artery stenosis were obtained at baseline, after laser angioplasty and after conventional angioplasty (if it was required). An attempt was made to use identical projections at the time each angiogram was obtained. Stenosis diameter and lesion length were usually measured with electronic or manual calipers at each center. Each angiogram coded as showing a perforation was reviewed by two of us (D.R.H., G.S.R.), and specific angiographic features were identified (Table 1). The lesion characteristics of the patients with perforation were then compared with the records of 195 patients who underwent excimer laser coronary angioplasty at the Mayo Clinic but did not have perforation. The arterial segments treated in these 195 patients were prospectively coded for lesion characteristics.

Table 1. Definition of Angiographic Morphology in Patients Treated With Excimer Laser Coronary Angioplasty

Feature	Comment
Lesion length	Discrete <10 mm; tubular 10 to 20 mm; diffuse >20 mm
Calcification	Patchy or nodular radiopaque deposits within the arterial wall
Eccentric	Lumen contained within outer one-third of diameter of apparently normal lumen
Bifurcation	Presence of a branch vessel originating at the target lesion
Ostial	Lesion to be treated arising at the ostium of the arterial segment
Angulation	Present when angle formed by the centerline through the lumen proximal to the stenosis and the centerline through the lumen distal to the stenosis forms an angle ≥45°

Definitions. A perforation was defined as the extraluminal, extravascular appearance of contrast medium. According to the prospective criteria of the Advanced Interventional Systems Registry, immediate laser success was defined as ≥20% reduction in the lumen diameter of the stenosis or a minimal lumen diameter >0.8 mm with a 1.3-mm catheter, >1 mm with a 1.6-mm catheter or >1.5 mm with a 2.0-mm catheter. A procedural success was defined as a diameter stenosis <50% at the end of the procedure (irrespective of whether coronary angioplasty was used), with no in-hospital death, coronary artery bypass grafting, Q wave myocardial infarction or need for an additional catheter revascularization procedure later during the hospital period.

Statistical analysis. The frequency of perforation was assessed over time in the Excimer Laser Coronary Angioplasty Registry. Differences in baseline characteristics between the patients with and those without perforation were assessed for the entire Registry. Specific lesion morphology and characteristics of the perforation were assessed by analysis of the patients with perforation and of 195 patients who underwent laser angioplasty at the Mayo Clinic but did not have perforation.

Continuous variables were expressed as mean value ± SD. Dichotomous variables were expressed as frequencies. Differences between groups were assessed with unpaired Student *t* test for continuous variables and Pearson chi-square analysis for dichotomous variables. The p values were two-tailed, and $p < 0.05$ was considered statistically significant.

Results

Of 2,759 consecutive patients who underwent excimer laser coronary angioplasty from August 24, 1988 to March 6, 1992, coronary artery perforation was identified in 36 (1.3%). The mean age was 63.1 years, and 22 patients (61%) were male. Ten patients (28%) had undergone previous coronary

JACC Vol. 23, No. 2
February 1994:330–5

Table 2. Arterial Segment Treated and Catheter Size Used in 2,759 Patients Who Had Excimer Laser Coronary Angioplasty

	Perforation (n = 36)		No Perforation (n = 2,723)		
	No.	%	No.	%	p Value
Treated segment					
LAD	19	53	1,007	37	< 0.02
RCA	9	25	790	29	NS
LCx	4	11	408	15	NS
Vein graft	3	8	436	16	NS
LMCA	1	3	82	3	NS
Catheter size (mm)					
1.3	7	19	602	22	NS
1.6	16	44	1,273	47	NS
2.0	11	31	714	26	NS
Unknown	2	6	133	5	NS

LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; LMCA = left main coronary artery; RCA = right coronary artery.

angioplasty, seven (19%) had undergone previous coronary artery bypass grafting.

The left anterior descending coronary artery was the most commonly treated vessel in patients with and without perforation (Table 2). In patients with perforation, the left anterior descending artery was more frequently treated (53% vs. 37%, $p < 0.02$). For the remaining vessels, the frequencies of treatment were similar between the two groups. There were no differences between the two groups in the catheter size used. A 1.6-mm catheter was used most frequently in each group (44% in the group with perforation, 47% in the group without perforation, p = NS).

The outcome of the procedure was substantially different between the two groups (Table 3). In patients with coronary artery perforation, treatment was based on the clinical setting. Typically, use of heparin was discontinued. If the perforation was broad based and large, particularly if ongoing ischemia was present, urgent coronary artery bypass grafting was usually performed. For patients in whom prolonged inflation was utilized, inflation times were maintained as long as possible, limited by clinical ischemia. Patients with perforation had markedly greater rates of coronary artery bypass grafting, myocardial infarction and death than did patients without perforation ($p < 0.001$). The procedure was successful and not associated with myocardial infarction, death or coronary artery bypass grafting in 93% of patients without perforation but in only 42% of patients with perforation ($p < 0.001$). In the patients with perforation who did not undergo coronary artery bypass grafting, adjunctive coronary angioplasty was always performed.

Table 3. Outcome in 2,759 Patients Who Had Excimer Laser Coronary Angioplasty

	Perforation (n = 36)		No Perforation (n = 2,723)		
	No.	%	No.	%	p Value
Event					
CABG	13	36.1	85	3.1	< 0.001
Q wave MI	6	16.7	105	3.8	< 0.001
Death	2	5.6	16	0.6	< 0.001
No MI, death or CABG	15	41.7	191	7.0	< 0.001
Adjunctive PTCA	26	72.2			
Successful procedure	15	42.0	2,532	93.0	< 0.001

CABG = coronary artery bypass grafting; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty.

The perforations ranged from small, discrete, extraluminal opacifications to large, more broadly based collections of contrast medium (Fig. 1 and 2). The perforation usually occurred in the lesion (63%), although in 22% it occurred distal to the lesion. In two patients, the perforation occurred in a chronic total occlusion after the guide wire had been passed. Whether the guide wire was initially subintimal in these patients could not be determined. In one patient, the movement of the laser catheter was filmed and appeared to be more rapid than the recommended 1 mm/s. A mean of 1.6 laser passes were made per lesion treated.

Comparison of the baseline lesion characteristics of the patients with perforations with those of the 195 Mayo Clinic patients who underwent excimer laser angioplasty but did not have a perforation (Table 4) showed that there were more angulated lesions and more ostial lesions in the patients who developed a perforation. However, the differences were not statistically significant.

The effect of increasing experience on the incidence of perforation was assessed in the larger group of 2,888 patients entered up to September 1992 in the Excimer Laser Coronary Angioplasty Registry. In this group, coronary artery perforation occurred in 1.2% overall. Perforation occurred in 1.6% of the first 1,888 patients and in only 0.4% of the last 1,000 patients ($p = 0.002$).

Discussion

Coronary artery perforation with conventional coronary angioplasty, although reported anecdotally, is extremely rare and is usually related to the guide wire rather than to the mechanism of dilation itself (1–8). In contrast, with laser angioplasty, tissue ablation itself may result in perforation. In an in vitro postmortem human heart study in which a 240-μm quartz optical fiber was used, perforation sites were characterized by extensive calcific deposits, side branch location and tortuous segments (10). Despite the high frequency in early in vitro studies with bare quartz fibers, with the more current technology used in the Excimer Laser Coronary Angioplasty Registry, coronary artery perforation was very uncommon, occurring in only 1.3% of 2,759 patients.

Identification of lesions at risk. Identification of lesions at risk for perforation remains difficult. Recently, Bittl et al. (17) reported a 3% rate of perforation in a group of 764 patients treated with another excimer laser system (Spec-

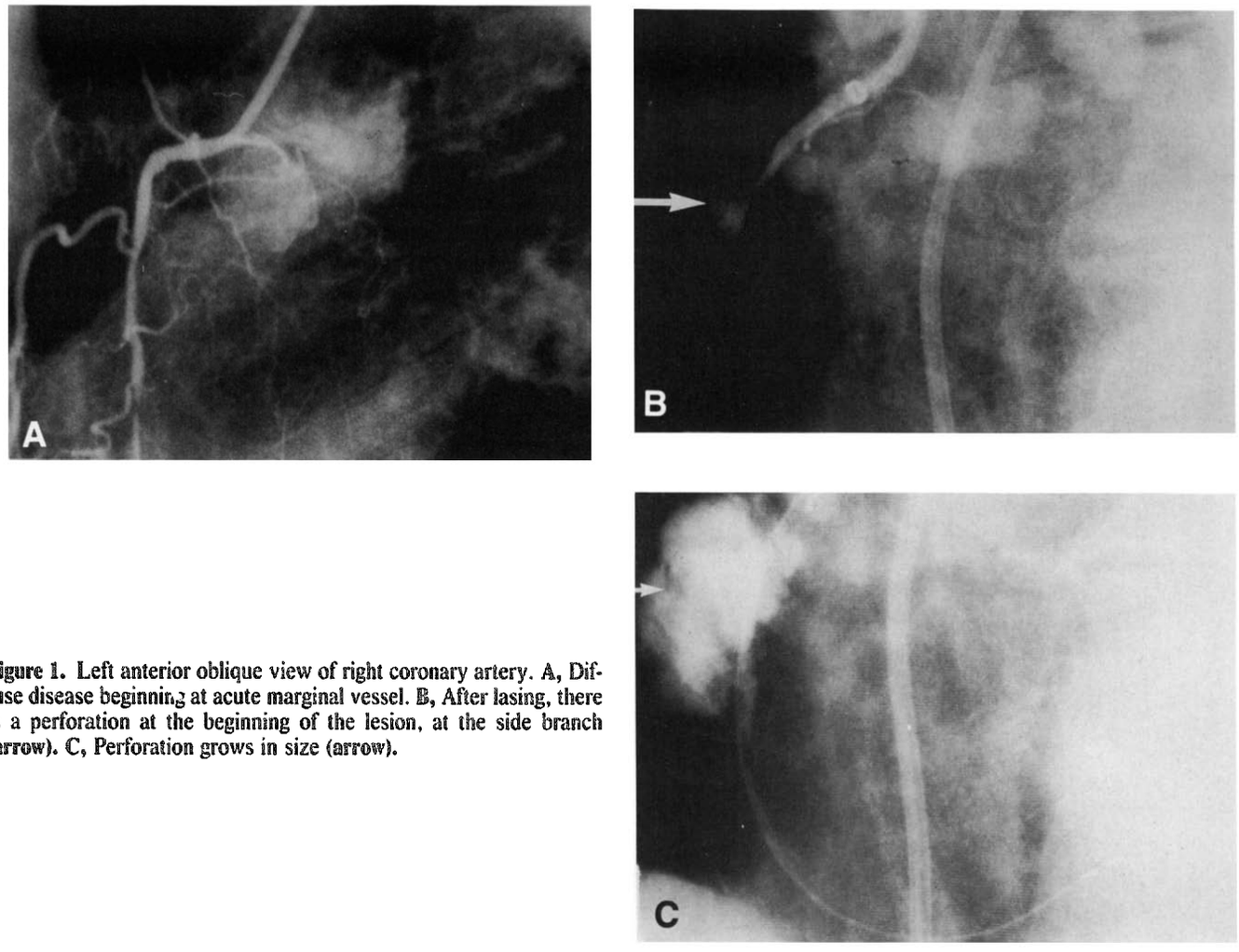

Figure 1. Left anterior oblique view of right coronary artery. A, Diffuse disease beginning at acute marginal vessel. B, After lasing, there is a perforation at the beginning of the lesion, at the side branch (arrow). C, Perforation grows in size (arrow).

tranetics Corp.). In their series of 23 patients, 14 had no clinical complications. Multivariate analysis documented bifurcation lesions to be associated with increased perforation, although the p value was only 0.049. In addition, vessel perforation was more common when the laser catheter was large relative to the diameter of the target vessel or when the vessel was small. In the present series, the latter factor was avoided. There were no other angiographic characteristics that predicted perforation in the analysis by Bittl et al. (17).

In the present series, identification of high risk lesions was difficult. Although the left anterior descending coronary artery was the most commonly treated segment in the patients who had perforation, it was also the most commonly treated segment in the patients who did not have perforation. There were no differences in the size of catheter used or in the number of lasing passes made. Identification of other procedural variables is difficult retrospectively. However, in one patient, advancement of the catheter was more rapid than is recommended, and in two patients, the perforation occurred during treatment of a chronic total occlusion. In these two patients, the wire may have been subintimal, and perforation was thus perhaps more likely. There were no other recorded procedural details that were different.

Specific lesion morphology could potentially confer an increased risk of perforation (10). In this series, our ability to predict complications on the basis of anatomy was limited. Although there were differences in lesion characteristics between patients with and without perforation, they were not statistically significant. Recently, the effect of morphologic predictors of immediate complications after excimer laser coronary angioplasty was analyzed in a multicenter experience of 200 patients who underwent 203 procedures using a centralized angiographic core laboratory (18). Lesions were divided into two groups: lesions associated with procedural complications (dissection, spasm, thrombus, embolus, aneurysm, acute occlusion, perforation, Q wave myocardial infarction or emergency coronary bypass surgery) and lesions not associated with complications. By univariate analysis, three factors were associated with one or more complication, including an abrupt proximal face of the lesion ($p = 0.051$), an eccentricity index of 30% ($p = 0.01$) and a larger proximal artery diameter ($p = 0.01$). By multivariate analysis, only the eccentricity index and proximal vessel diameter were important. Even though there was a statistically higher incidence of any complication with an eccentricity index ≥30%, 20% of patients with this charac-

JACC Vol. 23, No. 2
February 1994:330–5

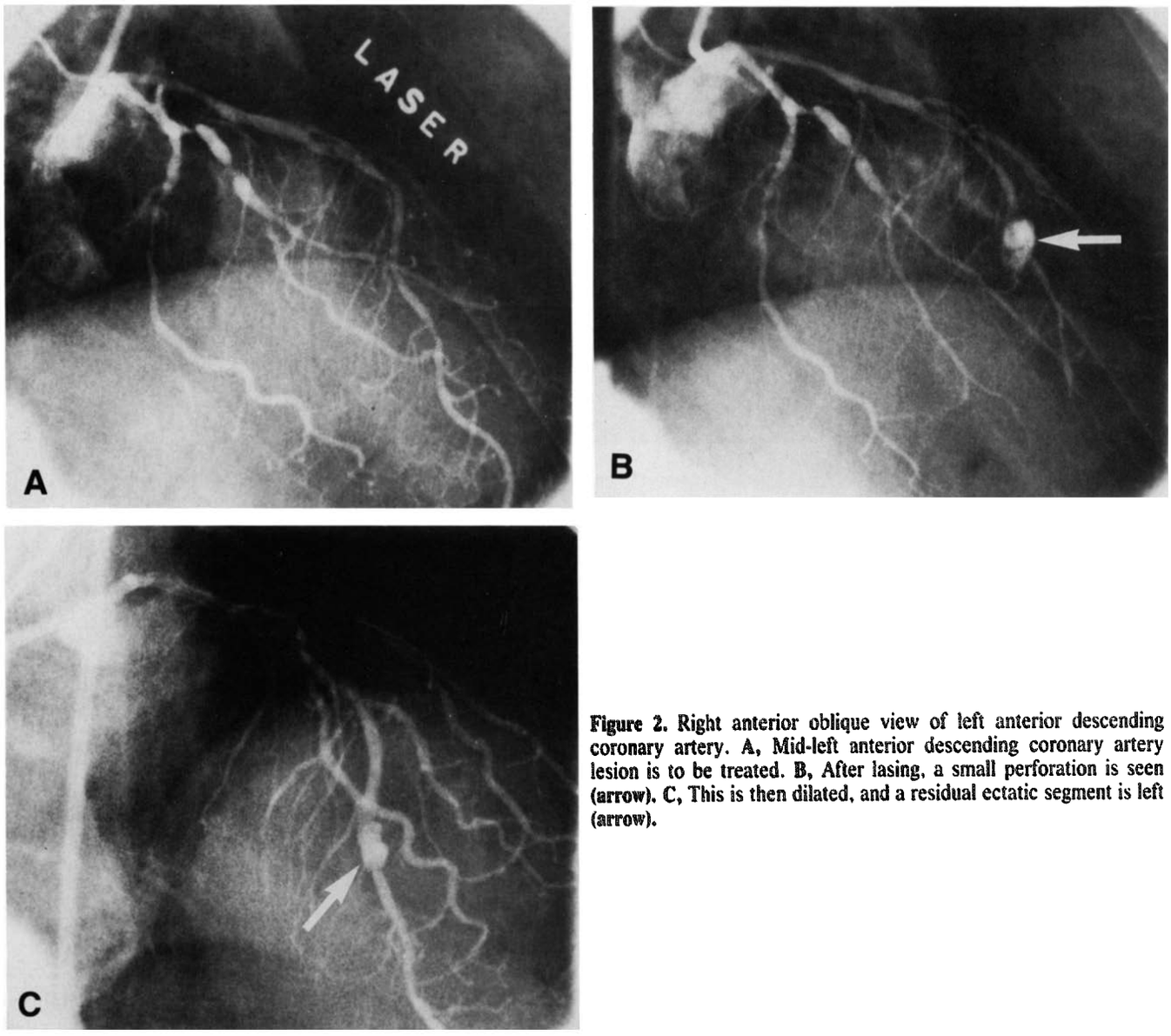

Figure 2. Right anterior oblique view of left anterior descending coronary artery. **A,** Mid-left anterior descending coronary artery lesion is to be treated. **B,** After lasing, a small perforation is seen (arrow). **C,** This is then dilated, and a residual ectatic segment is left (arrow).

teristic had a successful result with the laser procedure. In contrast, visual assessment of whether eccentricity was present usually had no predictive value. In the current series, the number of patients with perforation was small, and there were no significant lesion characteristics that identified patients at increased risk of perforation.

Table 4. Angiographic Characteristics in Patients Who Had Excimer Laser Coronary Angioplasty

Characteristic	Perforation (n = 36) No.	Perforation (n = 36) %	No Perforation (n = 195) No.	No Perforation (n = 195) %	p Value
Eccentric	15	42	97	50	0.48
Angulated >45°	11	31	37	19	0.18
Branch lesion	6	17	39	20	0.8
Ostial	5	14	14	7	0.3
Lesion morphology					
Discrete	14	39	68	35	
Diffuse	17	47	74	38	0.25
Tubular	5	14	52	27	

Outcome of perforation. When it occurs, perforation is variable in extent, from small, localized extravasation to tamponade. In this series, in-hospital event rates of coronary artery bypass grafting, infarction, and death were all markedly increased compared with rates in the control group. Two of the patients had a fatal outcome. Coronary artery bypass grafting was performed in 36% of patients with perforation but in only 3.1% of those without perforation. However, in 42% of patients, despite documented coronary perforation, myocardial infarction and the need for coronary artery bypass grafting were avoided. In these patients, adjunctive coronary angioplasty allowed stabilization of the angiographic findings and cessation of contrast extravasation.

Study limitations. There are several limitations of this study. The number of perforations was small, and a beta

error is possible. It is also possible that central reading of angiograms from all sites might have identified specific features. Patients were selected for the procedure at the operator's discretion. Patients with very eccentric lesions, severe bends or major branch involvement were usually not selected for the procedure, in part because of the concern with regard to the possibility of perforation or major dissection. Wider use of the device in these patients could have resulted in a higher incidence of perforation. In addition, there may be other, unmeasured anatomic features that result in the catheter being directed against the less involved wall rather than the wall with the most plaque burden Whether quantitative angiography or intravascular ultrasonography would help identify specific lesion characteristics cannot be determined from this series.

Changes in the technique—for example, changes in the speed of advancement—could have had an impact on perforation. There did appear to be a learning curve in either patient selection or technique to avoid or prevent perforation. Perforation occurred in 1.6% of the first 1,888 patients but in only 0.4% of the last 1,000 patients.

Conclusions. Coronary artery perforation is a rare complication of excimer laser coronary angioplasty, occurring in 1.3% of patients in the Registry. In addition, with increasing experience, the rate has decreased even further, to only 0.4% in the last 1,000 cases. When coronary artery perforation occurs, subsequent event rates are increased, although 40% of patients can be treated with conventional coronary angioplasty and have a good outcome.

Appendix

Centers Participating in the Excimer Laser Coronary Angioplasty Registry

Abbott Northwestern Hospital, Alvarado Hospital Medical Center, Baptist Medical Center of Oklahoma, Carolinas Medical Center, Cedars-Sinai Medical Center, The Christ Hospital, Daniel Freeman Memorial Hospital, Doctors Medical Center, Emory University School of Medicine, Georgetown University Hospital, Goleta Valley Community Hospital, Hillcrest Medical Center, Hoag Memorial Hospital-Presbyterian, Massachusetts General Hospital, The Mayo Clinic, Medical College of Virginia, The Mercy Hospital of Pittsburgh, The Methodist Hospital, Miami Heart Institute, Presbyterian Medical Center of Philadelphia, Robert Wood Johnson University Hospital, Rush-Presbyterian-St. Luke's Medical Center, St. Francis Regional Medical Center, Saint John's Hospital and Health Center, St. Luke's Hospital of Kansas City, St. Luke's Medical Center (Milwaukee), St. Luke's Medical Center (Phoenix), St. Vincent Hospital and Health Care Center, Shands Hospital University of Florida, South Miami Hospital, Summit Medical Center, The University of Alabama at Birmingham, University of Maryland at Baltimore, Washington Hospital Center, William Beaumont Hospital.

References

1. Kimbiris D, Iskandrian AS, Goel I, et al. Transluminal coronary angioplasty complicated by coronary artery perforation. Cathet Cardiovasc Diagn 1982;8:481–5.
2. Saffitz JE, Rose TE, Oaks JB, Roberts WC. Coronary arterial rupture during coronary angioplasty. Am J Cardiol 1983;51:902–4.
3. Meier B. Benign coronary perforation during percutaneous transluminal coronary angioplasty. Br Heart J 1985;54:33–5.
4. Grollier G, Bories H, Commeau P, Foucault JP, Potier JC. Coronary artery perforation during coronary angioplasty. Clin Cardiol 1986;9:27–9.
5. Goldman MH, Masden RR, Yared S. Acute rupture of the left anterior descending coronary artery secondary to percutaneous transluminal angioplasty. Am Heart J 1986;112:1325–8.
6. Steffenino G, Meier B, Finci L, et al. Acute complications of elective coronary angioplasty: a review of 500 consecutive procedures. Br Heart J 1988;59:151–8.
7. Nassar H, Hasin Y, Gotsman MS. Cardiac tamponade following coronary arterial rupture during coronary angioplasty. Cathet Cardiovasc Diagn 1991;23:177–9.
8. Gonzalez-Santos JM, Vallejo JL, Pineda T, Zuazo JA. Emergency surgery after coronary artery disruption complicating PTCA. Report of four cases. Thorac Cardiovasc Surg 1985;33:244–7.
9. Tomaru T, Geschwind HJ, Boussignac G, Lange F, Tahk SJ. Characteristics of shock waves induced by pulsed lasers and their effects on arterial tissue: comparison of excimer, pulse dye, and holmium YAG lasers. Am Heart J 1992;123:896–904.
10. Isner JM, Donaldson RF, Funai JT, et al. Factors contributing to perforations resulting from laser coronary angioplasty: observations in an intact human postmortem preparation of intraoperative laser coronary angioplasty. Circulation 1985;72 Suppl II:II-191–9.
11. Parker JD, Ganz P, Selwyn AP, Bittl JA. Successful treatment of an excimer laser-associated coronary artery perforation with the Stack perfusion catheter. Cathet Cardiovasc Diagn 1991;22:118–23.
12. Sanborn TA, Bittl JA, Hershman RA, Siegel RM. Percutaneous coronary excimer laser-assisted angioplasty: initial multicenter experience in 141 patients. J Am Coll Cardiol 1991;17 Suppl B:169B–73B.
13. Cook SL, Eigler NL, Shefer A, Goldenberg T, Forrester JS, Litvack F. Percutaneous excimer laser coronary angioplasty of lesions not ideal for balloon angioplasty. Circulation 1991;84:632–43.
14. Geschwind HJ, Dubois-Rande J-L, Zelinsky R, Morelle JF, Boussignac G. Percutaneous coronary mid-infra-red laser angioplasty. Am Heart J 1991;122:552–8.
15. Pacala TJ, McDermid IS, Laudenslager JB. Ultranarrow linewidth, magnetically switched, long pulse, xenon chloride laser. J Appl Physiol 1984;44:658–60.
16. Grundfest WS, Litvack F, Forrester JS, et al. Laser ablation of human atherosclerotic plaque without adjacent tissue injury. J Am Coll Cardiol 1985;5:929–33.
17. Bittl JA, Ryan TJ Jr, Keaney JF Jr, et al. Coronary artery perforation during excimer laser coronary angioplasty. J Am Coll Cardiol 1993;21:1158–65.
18. Ghazzal ZMB, Hearn JA, Litvack F, et al. Morphological predictors of acute complications after percutaneous excimer laser coronary angioplasty: results of a comprehensive angiographic analysis: importance of the eccentricity index. Circulation 1992;86:820–7.